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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,893	05/20/2008	Robert Graham Urie	EPCLP0122US	7532

23908 7590 08/30/2010

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EXAMINER	
LLOYD, EMILY M	

ART UNIT	PAPER NUMBER
3736	

MAIL DATE	DELIVERY MODE
08/30/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/597,893	URIE, ROBERT GRAHAM	
	Examiner	Art Unit	
	EMILY M. LLOYD	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 August 2006 and 07 July 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *11-17,19 and 22-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,18,20 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 August 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20060810*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I in the reply filed on 7 July 2010 is acknowledged.

2. Claims 11-17, 19 and 22-25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 7 July 2010.

Drawings

3. The drawings are objected to because page 9 lines 21-22 describe 45 as the inner sheath but Figure 4 does not show one sheath being inner and the other being outer as both element numbers 44 and 45 point to the outer sheath. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement

sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

4. The abstract of the disclosure is objected to because "finto" should be "into". Correction is required. See MPEP § 608.01(b).

5. The disclosure is objected to because of the following informalities: page 5 line 30 "solid core 8" should be "solid core 3"; and page 8 line 10 "distal end 5" should be "distal end 9".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10, 18, 20 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 states "the stiffness being defined as the force required to produce an angular lateral displacement of 30 degrees when applied at a distance of 10 mm along the respective length of guidewire." The Examiner notes that this could be interpreted as the stiffness being defined as the force required to produce a lateral bend of 30 degrees when the force is applied 10 mm from the end of a secured respective length of guidewire; however, given the word "along", which the dictionary defines as "in a line parallel with the length or direction of", this could also be interpreted as the stiffness being defined as the force required to produce an angular lateral displacement of 30 degrees when the force is applied throughout or over a length of 10 mm of the respective wire. The Examiner notes that Applicant's claim further does not provide complete details regarding where and how the guidewire is secured prior to the application of the force, if the force is applied distally of, proximally to, or between the location(s) where the guidewire is secured, and if the angular displacement is measured over any portion of the guidewire, over just the portion between the guidewire being secured and the force, or over the entirety of the guidewire on one side of where the guidewire is secured as compared to the other side of where the guidewire is secure. Claims 2-10, 18, 20 and 21 are rejected as ultimately depending on or incorporating claim 1.

Regarding claim 18, the it is unclear what "the distal end extends over a length of at least 2 cm" adds to the limitations of claims 1, 6 and 7, as claim 7 states that the distal end extends over a length of 12.5 ± 1 cm. Further, claims 1, 6 and 7 do not define

an intermediate portion. It is unclear if Applicant intended to define the intermediate portion as part of claim 18 or if claim 18 was intended to depend from a different claim.

Regarding claim 20, it is unclear what structural limitations this intended use adds to the limitations of claim 1. It is unclear if the guidewire of claim 1, as presented, has a stiffness adapted to do this function; if so, this claim would not further limit claim 1. Further, it is unclear if the diameter of the catheter sheath is an internal or external diameter, and if this diameter is intended to further limit the claim by limiting the size of a portion of the guidewire.

Regarding claim 21, it is unclear what structure is described by "to penetrate the supra-pubic region of the human body...". It is unclear if this is the catheter sheath; the internal diameter of the catheter sheath; the catheter sheath and the guidewire; the hollow needle, catheter sheath and guidewire; or another element or combination of elements. As such, it is unclear what elements provide this function, and what elements are further limited by the function.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-10, 18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over United States Patent Publication 2002/0156397 (Cornish).

Regarding claim 1, Cornish discloses a guidewire for introduction into a body via a hollow needle, comprising: a proximal end having a stiffness greater than the distal end (Figures 14 and 15), and the use of stiffness being defined as the force required to produce an angular lateral displacement of a specific amount when applied at a specific distance along the respective length of guidewire ([0068]).

Cornish does not specify the exact angle or distance used with regards to this definition of stiffness, and further do not specify their stiffness measurements based on this definition. However, the Examiner notes that Applicant's use of a specific angle and a specific distance in their definition of stiffness serve to specify quantities that would be predefined or chosen as described by Cornish [0068].

Further, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use an angular lateral displacement of 30 degrees and a distance of 10 mm because Applicant has not

disclosed that these particular values provide an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Cornish's stiffness definition and guidewire, and applicant's invention, to perform equally well with either the uniform (but not defined) quantities of Cornish or the claimed angular lateral displacement of 30 degrees and a distance of 10 mm because both criteria would perform the same function of allowing for consistent testing over numerous guidewires.

Therefore, it would have been prima facie obvious to modify Cornish to obtain the invention as specified in claim 1 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Cornish.

Further, as it is unclear what values are defined by Applicant's claim 1 (see the 35 USC 112 second paragraph rejection above), in an effort to expedite prosecution, the Examiner notes that the guidewire of Cornish, with comparative stiffness values as shown in Figures 14 and 15, appears to provide the stiffness requirements of Applicant's claim 1; the Examiner notes that Figure 15 in particular provides for a proximal end that is much stiffer than the distal end.

Regarding claim 2, Cornish teaches the guidewire of claim 1 further including an intermediate portion having a stiffness lying between the stiffness of the proximal end and the distal end (Figures 14 and 15).

Regarding claim 3, Cornish teaches the guidewire of claim 1 in which the distal end comprises a coil having a central core (Figure 1).

Regarding claim 10, Cornish teaches the guidewire of claim 1. Cornish does not expressly teach that the proximal end comprises a hollow tube containing a wire core. However, the Examiner takes Official Notice that it was well known in the art at the time the invention was made to use a proximal end comprising a hollow tube containing a core wire, as such a proximal tube provided for further changing or enhancing the material properties of the core wire at the proximal end. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to combine such a hollow tube containing a wire core at the proximal end with the invention of Cornish to provide for providing and increased and/or uniform stiffness at the proximal end of the guidewire.

Regarding claim 20, Cornish teaches the guidewire of claim 1 in which the proximal end has a stiffness adapted to facilitate the guiding of a substantially rigid catheter sheath of diameter in the range 5 to 7 mm into the bladder via the supra-pubic region of the human body (the Examiner notes that as this claim appears to provide an intended use for the guidewire of claim 1 but does not appear to require the guidewire to be stiffer than as claimed in claim 1, the guidewire of claim 1 meets this claim as it is capable of performing this function, see the rejections of claim 20 under 35 USC 112 second paragraph above); further, the Examiner notes that 5 mm is 0.197 inches; per Figure 13 of Cornish, the guidewire will fit into the catheter sheath.

The Examiner notes that claims 6, 7 and 18 are rejected under a first interpretation of the elements constituting the distal end and intermediate portion.

Regarding claim 6, Cornish teaches the guidewire of claim 1 in which the distal end extends over a length of between 10 and 15 cm ([0042] "distal core section has a first tapered segment 15 and a second tapered core segment 16.... two or more contiguous tapered core segments over a length of about 5 to 15 cm".

Regarding claim 7, Cornish teaches the guidewire of claim 6 in which the distal end extends over a length of 12.5 cm ± 1 cm (as the distal end can extend between 5 and 15 cm, it is inherent that it can extend over 12.5 ± 1 cm).

Regarding claim 18, Cornish teaches the guidewire of claim 7, in which the distal end extends over a length of at least 2 cm (see the rejections of claims 6 and 7 above) and in which the intermediate portion extends over a length of 4 cm ± 1 cm (an intermediate portion defined as the length of guidewire spanning 4 cm proximal to the proximal end of the distal end portion meets this limitation; as Cornish contains such a length of guidewire proximal to the proximal end of the distal end portion (as drawn, this would be the 4 cm of guidewire proximal to the proximal end of section 15 Figures 1 and 4), it meets this claim limitation).

The Examiner notes that claims 4, 5, 8 and 9 are rejected under a second interpretation of the elements constituting the distal end and intermediate portion.

Regarding claim 4, Cornish discloses that the guidewire of claim 2 in which the distal end and the intermediate portion (portions of guidewire corresponding to sections 18 and 16, respectively, note length lines in Figure 4; see Figures 1 and 4) comprise a coil (coil 14 Figures 1 and 4) having a central core (sections 16 and 18 Figures 1 and 4), the core having a first diameter in the intermediate portion greater than a second diameter in the distal portion (Figures 1 and 4).

Regarding claim 5, Cornish discloses the guidewire of claim 4 in which the central core has a tapering diameter in the intermediate portion towards the distal end (Figures 1 and 4).

Regarding claim 8, Cornish discloses the guidewire of claim 2 in which the distal end extends over a length of between 2 and 8 cm ([0046] "the overall length of the coil 14 is typically about 3 cm" which would provide for a length of distal tip 18 in the claimed range, see Figures 1 and 4), and in which the intermediate portion extends over a length of between 2 and 8 cm ([0043] "the first tapered segment is about 3 cm in length).

Regarding claim 9, Cornish discloses the guidewire of claim 8 in which the distal end extends over a length of at least 2 cm ([0046] "the overall length of the coil 14 is typically about 3 cm" which would provide for a length a length of distal tip 18 in the claimed range, see Figures 1 and 4)and in which the intermediate portion extends over a length of 4 cm ± 1 cm ([0043] "the first tapered segment is about 3 cm in length).

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cornish as applied to claims 1-10, 18 and 20 above, and further in view of United States Patent 6685671 (Oishi).

Regarding claim 21, Cornish teaches the guidewire of claim 1. Further, the Examiner notes that the use of a catheter sheath with a peelable outer skin is prior art (see page 1 line 22-page 2 line 7 of Applicant's specification). Cornish does not expressly teach that the guidewire forms part of a kit comprising: a hollow needle having an inside diameter adapted for receiving the guidewire; and a catheter sheath having an internal diameter adapted to receive the guidewire and to penetrate the supra-pubic region of the human body using the proximal portion of the guidewire as a guide, the catheter sheath having a peelable outer skin. Oishi teaches a guidewire (guidewire 8) that forms part of a kit comprising: a hollow needle having an inside diameter adapted for receiving the guidewire (puncturing needle 7, see also Column 6 lines 4-31); and a catheter sheath (sheath 10) having an internal diameter adapted to receive the guidewire (Column 6 lines 31-43) and to penetrate the supra-pubic region of the human body using the proximal portion of the guidewire as a guide (Column 6 lines 31-43, see also the abstract regarding the urinary bladder), the catheter sheath having a peelable outer skin (Column 7 lines 4-11; also admitted prior art). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the kit containing the elements taught by Oishi with the guidewire of Cornish as this would provide for using the advantages of a guidewire with linear changes in stiffness as taught by Cornish throughout various portions of the body (Oishi abstract).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to EMILY M. LLOYD whose telephone number is (571)272-2951. The examiner can normally be reached on Monday through Friday 8:30 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Emily M Lloyd
Examiner
Art Unit 3736

/EML/

/Max Hindenburg/

Supervisory Patent Examiner, Art Unit 3736